Interview: Jai Hiremath – Founder and MD; Sameer Hiremath – CEO and Joint-MD, Hikal, India



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Jai and Sameer Hiremath of Hikal provide insights into the main trends shaping the Indian and global CDMO industry. They articulate how Hikal's long-standing focus on quality standards, regulatory compliance, and good governance has enabled the company to avoid regulatory issues and gain the trust of the world's most respected pharmaceutical and crop protection companies, as Hikal reinvents itself and climbs up the value chain.

According to the 2016 Nice Insight CDMO Outsourcing survey, global pharmaceutical executives that still do not work with CDMO partners from emerging markets mention concerns related to regulatory compliance, intellectual property, and the difficulty of logistics. In this context, what has been your secret to draw the attention of some of the most prestigious multinational pharmaceutical companies?

Jai Hiremath (JH): The core of our company is chemistry. We first started operating in the crop sciences and veterinary field as a contract manufacturing organization, at the time where many Big Pharma companies still had strong in-house crop sciences divisions. Although we initially focused on intermediates, we steadily climbed up the value chain and expanded our company's scope of activities to include the manufacture of active ingredients. In 1995, we entered into a long term contract manufacturing agreement with Merck, Sharpe and Dohme (MSD) for the manufacturing of a veterinary and crop science product, which led us to build a significant greenfield production

facility specifically dedicated to this project. This partnership marked a significant milestone in our company's history, as setting up this manufacturing unit required an overall investment of over USD35 million in the mid 1990's.

In early 2000, Hikal moved into the pharmaceutical business – a field where we identified significant development opportunities for our company – while still growing our strong presence in the crop sciences arena too. In this regard, Hikal's successful track record as a reliable and quality supplier to the crop sciences industry gave us our entry into the pharmaceutical sector, as Big Pharma companies typically require the same quality standards from their suppliers, whether it relates to their crop sciences, veterinary, or human health divisions.

To sustain our entry into the pharmaceutical field, we acquired Novartis India's manufacturing site in the year 2000 when the global entities of Sandoz and Novartis merged A few years later, we further expanded our production capacity with the acquisition of a small Indian API company based in Bangalore, which had a R&D center and a single unit manufacturing facility. We transferred Hikal teams to this new plant, and they redesigned and built up the facility which subsequently became our company's first US FDA approved manufacturing site. Again, our expertise in chemical manufacturing as well as our knowledge of stringent regulatory requirements worldwide helped us to swiftly get this US FDA certification.

From MSD to Novartis, international innovators have historically been at the core of your customer basis. Is it still the case today?

JH: Recently, the US FDA audited our manufacturing facility and we received a clean EIR (establishment inspection report) report with "Zero 483's." In this regard, we proudly stand out as one of the few Indian manufacturers that has not received any warning letters from the US regulator, while the Indian industry at large has faced unprecedented regulatory difficulties over the past few years.

However, compliance issues affecting other Indian companies somewhat had a negative impact on global innovators' perception of Indian manufacturers, and it undoubtedly cooled down their eagerness to continue working with Indian companies. In this context, our company ultimately suffered from the recent deterioration of the "India brand".

Sameer Hiremath (SH): In the long run, we however consider that the difficult times experienced by the Indian industry will emerge as a window of opportunity for companies like Hikal: customers have become far more selective when it comes to choosing their Indian partners, which should further sharpen the attractiveness of our successful track record once the situation will be back to

normal.

JH: Overall, multinational companies are still at the core of Hikal’s strategy. However, due to this challenging industry context, we have been increasingly targeting export-oriented Indian companies, while the latter moreover offers several advantages: beside the geographical proximity, they are less exposed by M&A deals and changes of ownership.

In the meantime, we decided to increase our R&D efforts conducted in Hikal’s R&D center, with the objective to develop our own generic AI and API portfolio, both in crop sciences and the pharmaceutical business. Since 2015 we have filed a substantial amount of DMF’s with the US FDA, while we follow a life cycle extension strategy, where we focus on products that are about to go off patent.

Looking at the development of your own API portfolio, how are you taking into account the price erosion affecting regulated markets as well as the fierce competition from Chinese companies?

SH: Today, increased competition affects absolutely all product categories and molecules that will come off patent in the short, mid and long term. The large number of competitors however does not mean that all these companies will ultimately meet customers’ expectations in terms of quality, supply chain security or technology.

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In this regard, Hikal holds a unique advantage: we are the only company in India operating in both the pharmaceutical and crop protection business. When we started as an agrochemical company in 1991, our product portfolio at that time mainly comprised low price products, which forced us to look at the best engineering and manufacturing technologies to make this business sustainable. We maintained this strong focus on engineering excellence while developing our pharmaceutical business, which has truly allowed us to hold a greater control on our cost structure. We have even successfully developed several in-house manufacturing processes that received Indian and International awards.

In the meantime, we were among the first companies in India to embrace green manufacturing technologies, and an audit firm has been annually monitoring our company’s carbon footprint for several years already. In this regard, Hikal stands out as a Responsible Care company that truly shares the same values and approach of our multinational partners.

What is your take on the recent difficulties experienced by Indian companies with regards to regulatory compliance?

SH: First of all, one should remember that Indian manufacturers hold a critical importance in providing a large share of the world's population with life-changing medicines. The latter have been investing substantial resources in strengthening their compliance departments, and the number of warning letters received by Indian manufacturers has decreased over the past years.

JH: In this regard, I believe that our peers today have a better understanding of US FDA requirements, especially with regards to data integrity. As a matter of fact, most companies' facilities were cleared after re-inspections from the US FDA in the recent past.

Hikal is one of the few Indian companies with a strong export capacity that has never received any US FDA warning letters. How do you explain your excellent track record in this crucial aspect?

JH: We started partnering with leading multinational companies very early in our company's history, which forced us to comply with high standards and – above all – to instill a corporate mindset where quality standards and compliance are absolutely paramount. Regulatory and quality compliance truly comes as top-down endeavor.

One of the most serious regulatory issues faced by the Indian industry relates to data integrity; in this field, we ensure that no shortcuts are taken by our staff while providing them with the time and resources needed to respect and follow world-class standards. Our overall processes might be lengthier than those of our competitors, but at least we can be 100 percent sure that our company is totally compliant. At the end of the day, we prefer stopping the production to fix any issue that could arise rather than taking the risk to expose ourselves to compliance problems. This approach has been truly embedded within the company's way to do business over the past three decades.

SH: Since we introduced computer control systems in 1995, Hikal has been a frontrunner in India with regards to plant automation, and our fully automated units rely on a significantly smaller workforce than those of most Indian companies, which minimizes human operator error.

JH: This focus on quality is also reflected in our company's good governance approach and our efforts to institutionalize our structure with the help of some of the best experts globally. Just to give you a concrete example, Dr. Wolfgang Welter, one of our board members, has over 38 years of experience in the fine chemicals industry, and he was a board member responsible for industrial operations and quality, health, safety, environment at Bayer Crop Science for six years.

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SH: Furthermore, Hikal's R&D center was built under the supervision of Lonza's former Chief Technology Officer, Dr. Helmut Rupp who joined our company before retiring. This R&D center is today managed by Dr. Sudhir Nambiar, the former head of AstraZeneca India and prior to that the head of R&D at Novartis India. In all divisions, Hikal aims at attracting some of the best talent globally.

Given the on-going consolidation shaping the CDMO industry, what makes you believe that a large mid-size company like Hikal can continue thriving in an industry context increasingly dominated by large players?

JH: The consolidation shaping the CDMO sector will undoubtedly continue in the coming years, as these companies look at generating economies of scale. As per Hikal, we are not particularly worried by this industry trend, as the demand for our products and services is still particularly strong.

SH: Economies of scale do matter, but one should not overlook the importance of specialty companies holding differentiated technologies. In this regard, we see some Europe-based, mid-size CDMO companies with a specialty focus that have been doing really well, so it also proves that there is a room for niche players like us with a unique expertise and technology.

Indeed, customers are becoming more and more demanding, and the latter aim to partner with the world's best providers for a very precise part of the development and manufacturing process of a given molecule. In this context, we believe that a company like Hikal, which aims to position itself as one of the leading companies in the world in its own areas of expertise, clearly holds opportunities for growth moving forward.

Do you plan to exclusively rely on organic growth to propel the future growth of Hikal?

JH: There is clearly a shift among the Indian industry to set up manufacturing operations in the US or in Europe, with the objective to establish themselves as US or European manufacturers rather than *Make in India* companies. However, it is very expensive to build and run a plant overseas, especially in the US. As a result, I don't see how such an acquisition could be sustainable for a company of our size, while we hold enough land to organically expand our production capacity over the next four to five years. Beyond this date, we might consider acquiring a manufacturing plant that already complies with the most stringent standard, which would be more cost-efficient than a greenfield project.

SH: From a partnerships standpoint, we have been joining forces in specific areas such as R&D and technology development. For example, we are co-developing enzymatic chemistry hand-in-hand with a German company and several other European partners. In terms of R&D related co-development opportunities, we are truly looking at the best technologies in the world, regardless of the country or region of origin.

In a global context marked by increasing price pressure and decreasing margins, we foresee that companies holding basic technologies and focusing on low added-value products will struggle to comply with rising quality standards. In this regard, the only way forward is to continue climbing up the value chain and stimulate our company's innovation drive and we are doing this with over 20 percent of our employees who work in Research & Technology.

Tirelessly climbing up the value chain has become a necessity for Indian companies but this endeavor comes at a high cost. How could the Indian government better support domestic companies?

SH: We would like to see a better alignment between the government's R&D vision and the concrete tools and means that it brings to the table, especially when it comes to dedicated incentives. As a matter of fact, the Union government recently reduced the weighted tax deduction on R&D expenses from 200 percent to 150 percent as part of the Budget 2018, which is difficult to understand given our country's ambitions in the high-tech field.

India has incredibly talented people, and we see many Indian scientists pursuing prestigious careers among the world's leading multinational companies. I do believe that with the right incentives, the domestic industry will be able to develop the research infrastructure that would convince these scientists to stay in their home country.

Small molecules are expected to dominate the global CMO market even when projected out to 2021, with a share of 76 percent. However, biologics undoubtedly have wind in their sales, and the biologics CMO market was estimated at USD 5.3 billion in 2015. Shall we expect Hikal to venture into the biotech field in the coming years?

JH: At the moment, we mostly provide small molecule related CDMO services. It is true that biotech companies do stand as an attractive niche to service, as most of them do not hold in-house manufacturing facilities and therefore mostly rely on CDMO companies. We are already working with several US & European biotech companies for their small molecule portfolios.

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SH: As part of Hikal’s ten-year vision, we would want to be active in the biologicals business and we are currently exploring different development avenues to strengthen our presence in this field. A first step for us was to move into enzymatic chemistry, and we in the near future we will evaluate areas in the biologicals sphere, notably through partnerships. Our thinking moving forward will be to move from an R&D to a pilot scale, before gradually scaling up our capacity to the commercial stage.

Where would you like to see Hikal in the next five years?

JH: We want to continue growing at an annual growth rate of 15 to 20 percent, in line with the performance we have been displaying over the past five years. Fuelling our R&D pipeline will be absolutely crucial to fulfill this objective, which will require more and more investments dedicated to this specific field. To ramp up this process and increase our chances of success, we look at joining forces with companies that can help us improve our capacities and strengthen our company’s knowledge in some specific areas, such as continuous manufacturing.

SH: Our ambition is also to come closer to our customers: leveraging our strength in API’s & AI’s. As you know, actives make up a large share of finished products’ costs, and some customers have been asking us for quite a long time already to cover the entire value chain including formulations. At this time, we have ample opportunities to support our customers on the development and supply of actives in both our businesses while we continue to evaluate opportunities on a select basis for adding further value to our products.

Jai, successful first-generation entrepreneurs like yourself have truly built India’s pharmaceutical industry. What would be your piece of advice to second-generation executives that are now entrusted with the mission to drive these companies to new heights?

JH: One of the most crucial aspects is to never lose sight of the company’s values and standards. When a company’s business model is based on partnerships and long-standing business relationships, reliability is a key success factor that should never be neglected.

In the meantime, the new generation will have to be more innovative than ever, while reaching out to new geographies – such as Latin America and South East Asia – and diversifying the companies’

revenue streams.

Sameer, do you believe that it has become more difficult for Indian pharmaceutical executives of your generation to nurture the growth of their companies?

> “I believe it is clearly easier for businessmen of my generation to reach our growth objectives: our predecessors have done an incredible job in convincing leading multinational companies that they can rely on Indian partners and suppliers.”

SH: Quite the contrary! I believe it is clearly easier for businessmen of my generation to reach our growth objectives: our predecessors have done an incredible job in convincing leading multinational companies that they can rely on Indian partners and suppliers. A few decades ago, entrepreneurs had to sell the “*Brand India*” even before selling their own company…

Competition has definitely soared over the past decades, which means that more efforts and work is needed to achieve our results. Furthermore, evolving in an industry context where margins are decreasing means that we cannot afford any mistake, while grabbing current market opportunities require substantial investments in R&D and manufacturing technologies. Overall, the industry landscape is more complex, fragmented, and competitive while we operate in a high cost pressure environment.

Nevertheless, I am confident that Indian companies holding a critical size and a great reputation will continue thriving and moving forward – as long as they do not deviate from their core values and never compromise on quality.

What will be your final message to our international readers?

JH: Don’t paint all Indian companies with same brush: India truly holds islands of excellence that could emerge as partners of choice for the world’s best companies. When considering a country like India which holds thousands of companies operating in the pharmaceutical and fine chemicals field, international companies should not content themselves with the bigger picture. Although the remarkable density of our domestic industry means that some efforts might be required to identify partners that stand out from the crowd, it makes no doubt that these efforts will pay off at the end of the day.

SH: As per Hikal, we are a reliable manufacturer of fine chemicals in the crop sciences and pharmaceutical areas with a pristine track record of 30 years, a strong R&D capacity and a historic focus on regulatory compliance and good governance – and you should check us out!

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